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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 2

### Complete if Known

|                        |                     |
|------------------------|---------------------|
| Application Number     | 10/679,258          |
| Filing Date            | October 7, 2003     |
| First Named Inventor   | Krantz et al.       |
| Art Unit               | TO BE ASSIGNED 1631 |
| Examiner Name          | TO BE ASSIGNED CLOW |
| Attorney Docket Number | 51637/76            |

### U.S. PATENT DOCUMENTS

| Examiner<br>Initials * | Cite<br>No. <sup>1</sup> | Document Number                            | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of<br>Cited Document | Pages, Columns, Lines, Where Relevant<br>Passages or Relevant<br>Figures Appear |
|------------------------|--------------------------|--|--------------------------------|--|---|
|                        |                          | Number - Kind Code <sup>2</sup> (if known) |                                |  |   |
| LAC                    |                          | US-8,573,103B1                             | 06-03-03                       | Wald ✓ *   |   |
|                        |                          | US- 6,429,018B1                            | 08-08-02                       | Cole et al. ✓                                      |   |
|                        |                          | US- 6,025,149                              | 02-15-00                       | Cuckle et al. ✓                                    |   |
|                        |                          | US- 6,022,695                              | 02-08-00                       | Beard et al. ✓ *                                   |   |
|                        |                          | US- 8,010,912                              | 01-04-00                       | Davies ✓   |   |
|                        |                          | US- 5,908,944                              | 05-25-99                       | Davies ✓   |   |
|                        |                          | US- 5,834,317                              | 11-10-98                       | Davies ✓ *   |   |
|                        |                          | US- 5,840,586                              | 11-24-98                       | Davies ✓   |   |
|                        |                          | US- 5,716,853                              | 02-10-98                       | Cuckle et al. ✓                                    |   |
|                        |                          | US- 5,605,843                              | 02-25-97                       | Canick et al. ✓                                    |   |
|                        |                          | US- 5,324,868                              | 06-28-94                       | Macri ✓  |   |
|                        |                          | US- 5,324,667                              | 06-28-94                       | Macri ✓  |   |
|                        |                          | US- 5,316,953                              | 05-31-94                       | Macri ✓  |   |
|                        |                          | US- 5,258,907                              | 11-02-93                       | Macri ✓  |   |
|                        |                          | US- 5,252,489                              | 10-12-93                       | Macri ✓  |   |
| LAC                    |                          | US- 5,100,806                              | 03-31-92                       | Macri ✓  | blood<br>screens  |
|                        |                          | US-  |                                |  |   |
|                        |                          | US-  |                                |  |   |
|                        |                          | US-  |                                |  |   |
|                        |                          | US-  |                                |  |   |

### FOREIGN PATENT DOCUMENTS

| Examiner<br>Initials * | Cite<br>No. <sup>1</sup> | Foreign Patent Document   | Publication<br>Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited<br>Document | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear | T <sup>5</sup> |
|------------------------|--------------------------|---|-----------------------------------|---|--|----------------|
|                        |                          | Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>6</sup> (if known) |                                   |   |  |                |
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Examiner  
Signature

Lee A. Clow

Date  
Considered

12/3/04

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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**Complete if Known****INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 2

|                        |                     |
|------------------------|---------------------|
| Application Number     | 10/679,258          |
| Filing Date            | October 7, 2003     |
| First Named Inventor   | Krantz et al.       |
| Art Unit               | TO BE ASSIGNED 1631 |
| Examiner Name          | TO BE ASSIGNED Clow |
| Attorney Docket Number | 51637/76            |

**NON PATENT LITERATURE DOCUMENTS**

| Examiner<br>Initials * | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|------------------------|--------------------------|---|----------------|
| LAC                    |                          | MERKATZ IR, ET AL., "An association between low maternal serum alpha-fetoprotein and fetal chromosomal abnormalities," Am. J. Obstet. Gynecol., 148:888-894 (1984)  |                |
|                        |                          | STEMPFLE N., ET AL., "Skeletal abnormalities in fetuses with Down's syndrome: a radiographic post-mortem study," Pediatr. radiol., 29:682-688 (1999)  |                |
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| LAC                    |                          | PLATT L.D., ET AL., "Screening for Down syndrome with the femur length/biparietal diameter ratio: A new twist of the data," Am. J. Obstet. Gynecol., 167:124-128 (1992)   |                |
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Examiner  
Signature

Lori A. Clow

Date  
Considered

12/3/04

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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